

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NATERA, INC.,

Plaintiff,

v.

ARCHERDX, INC., ARCHERDX, LLC,
AND INVITAE CORPORATION

Defendants.

C.A. No. 20-cv-125-LPS
(Consolidated)

REDACTED - PUBLIC VERSION

**DEFENDANTS' RESPONSE TO PLAINTIFF'S JUNE 15, 2021
DISCOVERY DISPUTE LETTER**

Dated: June 16, 2021

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Attorneys for Defendants

Dear Chief Judge Stark,

Defendants ArcherDX, Inc., ArcherDX, LLC, and Invitae Corp. (together, “Archer”) write in response to Natera Inc.’s (“Natera”) June 15 letter seeking to compel certain discovery.

I. Deposition Scheduling

Natera demands that Archer provide it with dates for all of the depositions it has requested and designate witnesses for all of its proposed 30(b)(6) topics by “June 21 or within a shorter period of time.” Natera also demands that Archer “reach agreement” on dates for a cherry-picked subset of Natera witnesses, but not the numerous other important Natera witnesses for which Natera has remained silent, including the overwhelming majority of the 17 inventors on Natera’s patents. Natera’s one-sided proposal is unjustified and unreasonable.

There is no real dispute that the current case schedule is unworkable. It was not until May 28 (the Friday before Memorial Day) that the parties first served deposition notices. This was nearly a full month *after* the April 30 deadline for substantial completion of document production and only about a month before the July 9 close of fact discovery, an interval that spans two national holidays and the heart of the summer travel season. What’s more, counsel for Archer is scheduled for trial in July, which further complicates scheduling. Had Natera truly desired to complete depositions by July 9, it would not have waited so long to seek depositions. It cannot now cry prejudice and demand that Archer’s witnesses and their counsel jump to attention, juggle their schedules, and forego other obligations to satisfy Natera’s whim. As to 30(b)(6) topics, Natera boasts that it has designated witnesses for several topics, but Natera has not designated witnesses for 32 of the 51 topics Archer has served and is refusing outright to designate a witness for 24 topics. There has been no required meet and confer on 30(b)(6) topics pursuant to recently revised Rule 30. Again, the existing schedule is not realistic, and this situation is not, as Natera contends, due to any refusal by Archer to participate.

As reflected in the correspondence attached as Exhibit 1 to Natera’s letter, Archer agrees that the deposition scheduling process should start. D.I. 225, Ex. 1. But the parties need to know what the case schedule is before locking down dates. While Natera claims that it has proposed a reasonable schedule, it was actually Archer that originally did so. *Id.* Natera should agree to the revised schedule, and the parties should schedule depositions consistent with this.

II. Natera’s Demand For A Supplemental Response And Safe Harbor Uses

Natera demands that Archer provide a supplemental response regarding types of accused product uses that Archer contends fall under the Safe Harbor, as well as produce documents to show every use. Not only has Archer already agreed to supplement the response, it proposed this supplement in the first instance as a way of providing Natera the information it allegedly needed while avoiding burdensome and wasteful discovery. The supplemental response alone will address the issue raised; the document production will be of minimal value and is unduly burdensome.

Natera omits key information regarding the parties’ discussions on this issue and mischaracterizes Archer’s position. Significantly, in meet and confer, Archer offered to provide a supplemental response describing Archer’s internal activities relating to the accused products’ use that Archer contends falls under the Safe Harbor, thereby allowing Natera to assess Archer’s claim. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005) (“Each of the accused

activities must be evaluated separately to determine whether the exemption applies.” (emphasis added)). Instead of considering the proposal, *Natera rejected it* and moved to compel. By rejecting Archer’s proposal, only to propose the same solution later, Natera wastes the valuable time and resources of the Court and the parties. Natera’s attempt to paint Archer as the villain by accusing it of withholding information that would allow Natera to assess “whether such Accused Product uses are, or are not, legitimately protected under the [Safe Harbor]” is without merit. D.I. 225 at 2.¹

Natera also moves the Court to compel Archer to “produce documents . . . that shows [sic] the Accused Products’ uses . . . that may or may not be within the Safe Harbor,” arguing that those documents relate to “infringement, damages, and injunctive relief.” D.I. 225 at 2. If Archer provides the supplemental response describing Archer’s *activities*, there is no need for Archer to produce documents relating to every use for Natera to assess Safe Harbor designations. *See Merck*, 545 U.S. at 200 (requiring evaluation of the “activities” generally, not individual uses). Requiring Archer to produce documents pertaining to every use that falls under the Safe Harbor is of minimal value and is disproportionately burdensome.

For the particular uses at issue here, the circumstances are such that it poses a great burden to collect records that quantify the Safe Harbor uses, as Natera seeks. [REDACTED]

If the Court compels this production, Archer will dedicate substantial amounts of time and resources in collecting these records for Safe Harbor uses that Natera likely will not contest. Accordingly, Archer requests that the Court deny Natera’s motion to compel document production.

There can be no reasonable dispute that the types of uses Archer contends fall under the Safe Harbor are reasonably related to the development and submission of information under Federal law. [REDACTED]

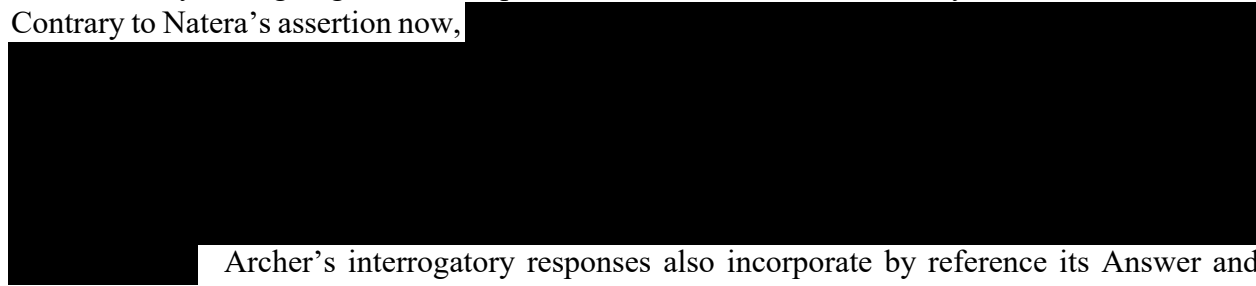
[REDACTED] Verification and validation studies are required as part of design controls required by the FDA under 21 CFR § 820.30(a)(1). Results from verification and validation studies are submitted for regulatory review as part of the Premarket Approval Application. *See* 21 CFR 814.20(b)(3)(v). Archer’s proposed supplemental response will give Archer the opportunity to provide Natera with these

¹ To the extent that Natera obliquely contends that Archer’s response to Interrogatory No. 2 is deficient, the Court has already addressed and denied Natera’s overbroad request relating to “every instance” of use. *See* D.I. 115. Archer then provided a fulsome response four months ago to Natera’s revised request, about which Natera has never complained. *See* Ex.5.

different categories of activities, such as the verification and validation studies, to demonstrate how the uses fall under the Safe Harbor.

III. Natera's Demand For Supplemental Responses To Interrogatory Nos. 10 And 11

Natera demands that Archer supplement its responses to Interrogatory Nos. 10 and 11. Such supplements are unwarranted at this juncture. Archer has provided substantive responses to Natera's contention Interrogatory Nos. 10 and 11 sufficient for this stage of litigation, given that fact discovery is ongoing, no fact depositions have been taken, and key facts lie with Natera. Contrary to Natera's assertion now,



Archer's interrogatory responses also incorporate by reference its Answer and Counterclaims, which provide specific grounds as well. *See* Ex. 7 (D.I. 21, ¶¶ 214-51 (Unclean Hands)); Ex. 8 (D.I. 21, ¶¶ 252-53 (Prosecution Laches)). This Court should reject Natera's premature demand.

IV. Natera's Demand Regarding RFP No. 9

Natera demands that Archer produce certain documents relating to RFP No. 9, a written representation of compliance, and even relief such as fees. This is unwarranted. The vast majority of documents at issue regarding six different customers were produced by April 30. Specifically, Natera has been in possession of all of the sales records for the six customers and the vast majority of agreements, statements of work, and technical materials since at least April 30.

Natera then said *nothing* for more than a month. It was not until June 2 that Natera sent an email raising a handful of minor issues with the production. *See* Ex. 6. The parties then scheduled a meet and confer, which was held last Thursday on June 10. In the interim, Archer worked diligently and swiftly to address issues in Natera's email, including a technical production issue. Then, during the meet and confer, Archer stated that it would look into the small number of outstanding issues Natera raised, and Archer has continued to promptly address these issues. For example, Natera stated that it did not have one of the dozens of agreements Archer agreed to produce. *Id.* Archer produced that agreement yesterday. Archer also produced the remaining documents from one customer. Notably, for that specific customer, Natera had already been in possession of the majority of documents since before April 30, including the master agreement and purchase orders by virtue of a third party subpoena, as well as sales figures, protocols, and product inserts.

Natera's letter includes no explanation for why it needed to burden the Court *one day* after the parties' meet and confer and after it waited more than a month to even raise the issues. Natera's suggestion of "fees for necessitating additional motion practice" without identifying any particular piece of information it does not believe it will receive following meet and confer is unwarranted and reflective of Natera's overly aggressive discovery stance. Natera's request should be denied.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (Via E-Mail)

EXHIBIT 1

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NATERA, INC.,

Plaintiff / Counterclaim-Defendant,

v.

ARCHERDX, INC., ARCHERDX, LLC, and
INVITAE CORP.

Defendants / Counterclaimants.

Case No. 20-125 (LPS)
CONSOLIDATED

JURY TRIAL DEMANDED

**DECLARATION OF JUSTIN R. SMITH IN SUPPORT OF DEFENDANTS' RESPONSE
TO NATERA INC.'S JUNE 15 LETTER**

I, Justin R. Smith, declare as follows:

1. I am currently the IVD Quality Assurance Operation Lead at Invitae Corporation.

I have served in this position since March 29, 2021. I have personal knowledge of the facts stated in this declaration and, if called as a witness, I could and would testify competently thereto.

2. I understand Natera is seeking detailed information regarding individualized instances of when Archer has used certain products and the records reflecting those uses.

3. It would be a challenging, manual, and time-intensive process to identify and collect the records sought.

4. [REDACTED]

[REDACTED]

[REDACTED]

5. [REDACTED]

[REDACTED]

[REDACTED]

6. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

7. [REDACTED]

[REDACTED]

Dated: June 16, 2021

ArcherDX, Inc., ArcherDX, LLC,
Invitae Corp
Defendants

By: /s/ Justin R. Smith
Justin R. Smith
IVD Quality Assurance
Operation Lead

EXHIBIT 2

REDACTED

IN ITS

ENTIRETY

EXHIBIT 3

REDACTED

IN ITS

ENTIRETY

EXHIBIT 4

REDACTED

IN ITS

ENTIRETY

EXHIBIT 5

REDACTED

IN ITS

ENTIRETY

EXHIBIT 6

**REDACTED
IN ITS
ENTIRETY**

EXHIBIT 7

THIRTEENTH DEFENSE
(Unclean Hands)

214. Natera's patent infringement claims are barred in whole or in part under the doctrine of unclean hands.

The '814 Patent and The '172 Patent

215. As particularized below, the '814 Patent and the '172 Patent are the results of protracted and convoluted prosecution at the USPTO spanning more than a decade, and involving 16 provisional patent applications and 10 continuation or continuation-in-part applications, almost half of which were abandoned.

216. The '814 Patent and the '172 Patent are continuations of U.S. Patent App. No. 16/140,298 filed September 24, 2018.

217. U.S. Patent App. No. 16/140,298 is a continuation of U.S. Patent App. No. 14/918,544, filed October 20, 2015.

218. U.S. Patent App. No. 14/918,544 is a continuation-in-part of U.S. Patent App. No. 14/877,925, filed October 7, 2015, which is now abandoned; a continuation-in-part of U.S. Patent App. No. 14/692,703, filed April 21, 2015; and a continuation-in-part of U.S. Patent App. No. 14/538,982. U.S. Patent App. No. 14/918,544 claims priority to U.S. Provisional App. No. 62/147,377, filed April 14, 2015; U.S. Provisional App. No. 62/146,188, filed April 10, 2015; and U.S. Provisional App. No. 62/066,514, filed October 21, 2014.

219. U.S. Patent App. No. 14/877,925 is a continuation-in-part of U.S. Patent App. No. 14/255,356, filed March 25, 2014, which is now abandoned after the applicant failed to respond to any office action in prosecution; a continuation-in-part of U.S. Patent App. No. 13/780,022, filed February 28, 2013, which is now abandoned; and a continuation of U.S. Patent App. No. 13/683,604, filed November 21, 2012, which is now abandoned.

220. U.S. Patent App. No. 14/692,703 claims priority to U.S. Provisional App. No. 62/148,173, filed April 15, 2015; U.S. Provisional App. No. 62/147,377, filed April 14, 2015; U.S. Provisional App. No. 62/146,188, filed April 10, 2015; U.S. Provisional App. No. 62/066,514, filed October 21, 2014; U.S. Provisional App. No. 61/994,791, filed May 16, 2014; U.S. Provisional App. No. 61/987,407, filed May 1, 2014; and U.S. Provisional App. No. 61/982,245, filed April 21, 2014.

221. U.S. Patent App. No. 14/538,982 claims priority to U.S. Provisional App. No. 62/066,514, filed October 21, 2014; U.S. Provisional App. No. 61/994,791, filed May 16, 2014; U.S. Provisional App. No. 61/987,407, filed May 1, 2014; and U.S. Provisional App. No. 61/982,245, filed April 21, 2014.

222. U.S. Patent App. No. 14/255,356 is a continuation of PCT Application PCT/US2012/58578, filed October 3, 2012.

223. U.S. Patent App. No. 13/780,022 is a continuation-in-part of U.S. Patent App. No. 13/683,604, filed November 21, 2012, which is now abandoned; a continuation-in-part of PCT Application No. PCT/US2012/58578, filed October 3, 2012; a continuation-in-part of U.S. App. No. 13/335,043, filed December 22, 2011; a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; and a continuation-in-part of U.S. App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/634,431, filed February 29, 2012.

224. U.S. Patent App. No. 13/683,604 is a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; a continuation-in-part of U.S. App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/675,020, filed July 24, 2012.

225. PCT Application PCT/US2012/58578 is a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; and claims priority to U.S. Provisional App. No. 61/683,331, filed August 15, 2012; and U.S. Provisional App. No. 61/542,508, filed October 3, 2011.

226. U.S. Patent App. No. 13/335,043 is a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; a continuation-in-part of U.S. Patent App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/426,208, filed December 22, 2010.

227. U.S. Patent App. No. 13/300,235 is a continuation-in-part of U.S. Patent App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/542,508, filed October 3, 2011; and U.S. Provisional App. No. 61/571,248, filed June 23, 2011.

228. U.S. Patent App. No. 13/110,685 claims priority to U.S. Provisional App. No. 61/516,996, filed April 12, 2011; U.S. Provisional App. No. 61/448,547, filed March 2, 2011; U.S. Provisional App. No. 61/462,972, filed February 9, 2011; U.S. Provisional App. No. 61/398,159, filed June 21, 2010; and U.S. Provisional App. No. 61/395,850, filed May 18, 2011.

229. In connection with the above applications, Natera filed *hundreds* of proposed claims with the USPTO.

230. Prior to the filing of the '814 Patent application and the '172 Patent application on April 30, 2019, Natera had *never* disclosed nor sought claims corresponding to the claims of the '814 Patent or '172 Patent.

231. On information and belief, Natera drafted the claims of the '814 Patent and the '172 Patent in an egregious attempt to cover ArcherDX's proprietary AMPTM process—a method of amplifying DNA that Natera did not invent.

232. Indeed, Natera filed the '814 and the '172 Patent applications only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's Accused Products and then returned to Natera.

The '482 Patent

233. As particularized below, the '482 Patent is the result of protracted and convoluted prosecution at the USPTO spanning close to a decade, and involving 8 provisional patent applications and 4 continuation or continuation-in-part applications.

234. The '482 Patent is a continuation of U.S. Patent App. No. 16/012,667 filed June 19, 2018.

235. U.S. Patent App. No. 16/012,667 is a continuation of U.S. App. No. 13/335,043, filed December 22, 2011; a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; and a continuation-in-part of U.S. App. No. 13/110,685, filed May 18, 2011.

236. U.S. Patent App. No. 13/335,043 is a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; a continuation-in-part of U.S. Patent App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/426,208, filed December 22, 2010.

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238. U.S. Patent App. No. 13/110,685 claims priority to U.S. Provisional App. No. 61/516,996, filed April 12, 2011; U.S. Provisional App. No. 61/448,547, filed March 2, 2011;

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239. In connection with the above applications, Natera filed *hundreds* of proposed claims with the USPTO.

240. Prior to the filing of the '482 Patent application on April 30, 2019, Natera had *never* disclosed nor sought claims corresponding to the claims of the '482 Patent.

241. On information and belief, Natera drafted the claims of the '482 Patent in an egregious attempt to cover ArcherDX's proprietary AMPTM process—a method of amplifying DNA that Natera did not invent.

242. Indeed, Natera filed the '482 Patent application only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's Accused Products and then returned to Natera.

The '708 Patent

243. As particularized below, the '708 Patent is the result of protracted and convoluted prosecution at the USPTO for close to 6 years, and involving multiple provisional and continuation patent applications.

244. The '708 Patent is a continuation of U.S. Patent App. No. 15,336,630 filed October 27, 2016; a continuation of application No. 14/538,982, filed on November 24, 2014.

245. U.S. Patent App. No. 14/538,982 claims priority to U.S. Provisional App. No. 62/066,514, filed October 21, 2014; U.S. Provisional App. No. 61/994,791, filed May 16, 2014; U.S. Provisional App. No. 61/987,407, filed May 1, 2014; and U.S. Provisional App. No. 61/982,245, filed April 21, 2014.

246. Prior to the filing of the '708 Patent application on April 30, 2019, Natera had *never* disclosed nor sought claims corresponding to the claims of the '708 Patent.

247. On information and belief, Natera drafted the claims of the '708 Patent in an egregious attempt to cover ArcherDX's proprietary AMPTM process—a method of amplifying nucleic acids that Natera did not invent.

248. Indeed, Natera filed the '708 Patent application only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's Accused Products and then returned to Natera.

249. Moreover, on information and belief, Natera knew or should have known that the Asserted Patents are invalid under at least 35 U.S.C. §§ 101 and 103 given Natera's own admissions made in court filings in this District and elsewhere, representative examples of which are set forth below in ArcherDX's Counterclaims.

250. On information and belief, Natera has improperly sought to delay competition in the IVD market by pursuing patent claims it did not invent, and subsequently prematurely asserting invalid patents that do not cover ArcherDX's products in development.

251. Based on the foregoing business misconduct, the relief Natera seeks in this action is barred by reason of its unclean hands.

FOURTEENTH DEFENSE
(Prosecution Laches)

252. Natera's patent infringement claims are barred in whole or in part under the doctrine of prosecution laches.

253. As described above, on information and belief, Natera engaged in an unreasonable and undue delay in the prosecution of the Asserted Patents, which has prejudiced

EXHIBIT 8

246. Prior to the filing of the '708 Patent application on April 30, 2019, Natera had *never* disclosed nor sought claims corresponding to the claims of the '708 Patent.

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248. Indeed, Natera filed the '708 Patent application only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's Accused Products and then returned to Natera.

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(Prosecution Laches)

252. Natera's patent infringement claims are barred in whole or in part under the doctrine of prosecution laches.

253. As described above, on information and belief, Natera engaged in an unreasonable and undue delay in the prosecution of the Asserted Patents, which has prejudiced

ArcherDX. Thus, as a matter of equity, the Asserted Patents cannot be enforced against ArcherDX.

ARCHERDX'S COUNTERCLAIMS

Defendant / Counterclaimant ArcherDX, Inc. ("ArcherDX") asserts Counterclaims against Plaintiff / Counterclaim-Defendant Natera, Inc. ("Natera") as follows:

NATURE OF ACTION

1. For its Counterclaims, ArcherDX seeks declarations that its LIQUIDPlexTM, FusionPlexTM and VariantPlexTM products do not infringe U.S. Patent No. 10,538,814 ("the '814 Patent"), United States Patent No. 10,557,172 ("the '172 Patent"), United States Patent No. 10,590,482 ("the '482 Patent"), and United States Patent No. 10,597,708 ("the '708 Patent") (collectively, the "Asserted Patents") and that the Asserted Patents are invalid.

PARTIES

2. ArcherDX is a Delaware corporation with a principal place of business at 2477 55th Street, Suite 202, Boulder, Colorado 80301.

3. On information and belief, and as alleged by Natera in its First Amended Complaint, Natera is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 201 Industrial Road, San Carlos, California 94070.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as to ArcherDX's counterclaims against Natera pursuant to the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment